

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference P200301958 WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/DK 03/00791	International filing date (<i>day/month/year</i>) 19.11.2003	Priority date (<i>day/month/year</i>) 19.11.2002
International Patent Classification (IPC) or both national classification and IPC A61B8/12		
Applicant RHINOMETRICS AS et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

I ☒ Basis of the opinion

II ☐ Priority

III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability



IV ☐ Lack of unity of invention

V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

VI ☐ Certain documents cited

VII ☐ Certain defects in the international application

VIII ☐ Certain observations on the international application

Date of submission of the demand 07.06.2004	Date of completion of this report 05.01.2005
Name and mailing address of the international preliminary examining authority: <div style="margin-left: 20px;">  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 </div>	Authorized Officer Kempin, H-F Telephone No. +49 89 2399-2716 <div style="text-align: right;">  </div>

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/DK 03/00791

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

Description, Pages

1-9 as originally filed

Claims, Numbers

8 (part), 9 as originally filed
1-7, 8 (part) filed with telefax on 12.11.2004

Drawings, Sheets

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

see separate sheet

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-9
	No: Claims	
Inventive step (IS)	Yes: Claims	4-6
	No: Claims	1-3,8,9
Industrial applicability (IA)	Yes: Claims	1-9
	No: Claims	

2. Citations and explanations

see separate sheet

Unallowable amendment (Rule 70.2 c) PCT)

The applicant has amended claim 1 by inserting the feature 'unsupported' before 'flexible and essentially non-stretchable'. The term 'unsupported' does not appear anywhere in the description or claims and can thus only be derived from the figures under due consideration of the other parts of the disclosure. However, it is considered that the skilled person, when looking at the figures, in particular figures 7-12, would not be in a position to derive directly and unambiguously the feature 'unsupported'.

Consequently, according to Rule 70(2) c) PCT this report is established as if the amendment had not been made.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1.1 Reference is made to the following documents:

D1: US-A-5 823 965;

D2: WO-A-92/20397

The documents were not cited in the international search report (Document D1 is cited in the description of the present application on page 1; document D2 is cited from the examiner's knowledge).

1.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.**

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):

An inflatable catheter with a proximal end and a closed distal end for inserting into a human or animal body cavity, the catheter having at least a longitudinal, inflatable section that is flexible and which collapses when not inflated (see figure 7 in connection with column 6, lines 30-40).

The subject-matter of claim 1 therefore differs from this known catheter in that the inflatable section is essentially non-stretchable.

The problem to be solved by the present invention may therefore be regarded as providing an inflatable section which, when inflated, adapts more closely to the sidewall of the body cavity without deforming it.

The solution proposed in claim of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons.

In document D1 it is -in connection with the construction of the balloon- expressly referred to normal catheter technique for widening blood vessels. Document D2 relates to this kind of catheter so that it would be considered by the skilled person. On page 10, lines 12-15 it is disclosed that a balloon is made of a non-elastomeric material which does not substantially stretch beyond a predetermined maximum diameter as pressure is increased. Consequently, claim 1 does not satisfy the requirement of Art.33(3) PCT (inventive step).

1.2 A fluid pump for inflating the catheter is also known from D1, column 6, lines 59-65 so that the same reasoning as under point 1.1 applies to the subject-matter of the corresponding independent **claim 8, which therefore is also considered not inventiv** .

1.3 Dependent **claims 2, 3 and 9 do not** contain any features which, in combination with the features of any claim to which they refer, **meet the requirements of the PCT in respect of inventive step.**

claim 2: see D2, page 10, lines 15-27;

claim 3: The claimed thickness range is within the normal range of polymer foils.

claim 9: Controllable fluid pumps are generally well known in the art.

1.4 The combination of the features of dependent claims 4-6 is neither known from, nor rendered obvious by, the available prior art. The available prior art does not mention the use of a web of material for the inflatable section, in connection with the features of claim 1, which design has the advantages set out in the description of the present application on page 1, third paragraph. **A new main claim which combines the features of claims 1 and 4 would thus satisfy Art.33(3) PCT, as would claims 5 and 6 if they were appended to such a new main claim.**

Claims 8 and 9, if referring back to catheter claims modified as indicated here-

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above, would then also satisfy the requirement of Art.33(3) PCT.

Further observation

It is noted that a **passage of the description is missing** on page 6 after line 2. The description jumps from figure 1 to figure 4.

CLAIMS:

1. An inflatable catheter (1) with a proximal end (A) and a closed distal end (B) for inserting into a human or animal body cavity, the catheter having at least a longitudinal, inflatable section that is flexible and essentially non-stretchable and which collapses when not inflated. *Y unsupported,*
2. A catheter according to claim 1 wherein the inflatable section comprises a material chosen among LDPE, HDPE, PET, polyetan, polyurethane and other materials with similar mechanical properties.
3. A catheter according to claim 1, where the inflatable section comprises a material having a thickness between 10 and 100 μm , preferably between 10 and 50 μm .
4. A catheter according to any one of claims 1 - 3, wherein the inflatable section comprises a web of material with opposing edges secured to each other.
5. A catheter according to claim 4, wherein the web is of a weldable material, and the opposing edges are secured to each other by welding.
6. A catheter according to claim 5 having two or more lumens separated by welding seams.
7. A catheter according to any one of claims 1 - 6 comprising a tubular member at the proximal end (A).
8. A device for measuring in human or animal body cavities, the device comprising catheter (1) with a proximal end (A) and a closed distal end (B) for inserting into the body cavity, a fluid pump for inflating the catheter and